UNITED STATES FOOD AND DRUG ADMINISTRATION

Administrative Practices and Procedures;
Formal Hearings

OMB Control No. 0910-0191 - Revision

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations found in 21 CFR Part 10, 21 CFR Parts 12 through 16, and 21 CFR Part 19 (21 CFR §§ 10, 12-16, and 19). These regulations are established in accordance with the Administrative Procedures Act and implement administrative practice and procedures to give instructions to those conducting business with FDA. Regulations in part 10 (21 CFR Part 10) describe general administrative practices and include content and format instruction on submitting information to the agency, petitions for agency action, and other topics such as the public calendar. Regulations in 21 CFR parts 12 through 16 cover formal evidentiary, public, and regulatory hearings. We are revising the collection to account for burden associated with waiver requests under part 10.19. Unless a waiver, suspension, or modification submitted under § 10.19 (21 CFR 10.19) is granted by the Commissioner of Food and Drugs (the Commissioner), the regulations in 21 CFR part 10 apply to all petitions, hearings, and other administrative proceedings and activities conducted by FDA. Because we have not received requests under § 10.19, we had not included this provision in the information collection. However, to reflect the attendant burden resulting from submitting such a request, we provide an estimate of 1 response and 1 burden hour annually, as reflected below in this supporting statement. Also, because most information associated with regulations in parts 12-16 is obtained during the conduct of an official administrative action as described under 5 CFR 1320.4, we only include burden associated with initiating hearings pursuant to the applicable regulations.

We are also revising the collection to account for burden associated with general meeting requests and correspondence under section 10.65 (21 CFR 10.65) and general submissions associated with section 10.115 which provides for public participation in the development of agency guidance documents through requests to our Dockets Management Staff. Although most submissions and attendant burden associated with recommendations found in FDA guidance documents is accounted for in topic-specific and approved ICRs, here we are accounting for burden associated with general public submissions as described in § 10.115(f)(3).

We are also revising the collection to include agency guidance entitled, "*Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.*" The guidance was issued consistent with our Good Guidance Practice

regulation in 21 CFR 10.115, which provides for public comment at any time. The guidance document provides information regarding our current thinking on interpreting section 505(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(q)) and includes procedural instruction on certain citizen petitions and petitions for stay of FDA action. The

guidance document also describes how FDA interprets the provisions of section 505(q) requiring that (1) a petition include a certification and (2) supplemental information or comments on a petition include a verification. It also addresses the relationship between the review of petitions and pending ANDAs, 505(b)(2) applications, and 351(k) applications for which a decision on approvability has not yet made. Information collection activity discussed in the guidance document is currently approved under OMB control number 0910-0679, however for operational efficiency were are consolidating the collection here. Additionally, we have revised the guidance document to describe some of the considerations FDA will take into account in determining whether a petition is submitted with the primary purpose of delaying the approval of an application under section 505(q)(1)(E) of the FD&C Act.

Accordingly we are requesting OMB approval for the information collection provisions with the regulations and associated guidance document discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use the information collection in support of agency operations to determine and direct as appropriate throughout the agency, requests for FDA action; to plan and coordinate agency efforts in responding to such requests; and to best utilize agency resources to promote and administer protections to the public health. The data from petitions and other requests received by the agency helps us identify areas of both interest and concern to those who consume the products regulated by FDA.

3. Use of Improved Information Technology and Burden Reduction

Most business with FDA is conducted electronically reflecting current standard business practice. Where possible and as resources permit, we continually seek ways to improve operational efficiencies with available technologies and user applications, as well as the most cost effective implementation methods. We routinely invite and encourage ideas and comments in this regard in notices published by the agency.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection does not pose undue burden on small entities. Provisions in part 10.19 (21 CFR § 10.19) allow for waived, suspended, or modified procedures. In addition, we provide resources and instruction on our website at www.fda.gov regarding submissions to FDA.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden. This information collection is established and maintained to support requests *of* the agency and provide for public participation in agency activities. The collection schedule is determined by respondents.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the Federal Register of January 9, 2020 (85 FR 1169). Although two comments were received, neither was directly responsive to the information collection topics solicited. At the same time, the comments were supportive of FDA information collection activity and we appreciate this input.

Also, our regulations at 21 CFR § 10.115 provide for the development and issuance of agency guidance documents intended to assist respondents with information collection activity undertaken by the agency and provide for public comment at any time.

9. Explanation of Any Payment or Gift to Respondents

No gift or payment is provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality has been provided except as provided in 21 CFR 20.61 and generally considered in reviewing data and information submitted to FDA. Notices received by the agency are publicly available.

11. Justification for Sensitive Questions

The information collection contains no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Burden:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
10.19; request for waiver, suspension, or modification of requirements	1	1	1	1	1
10.30 and 10.31; citizen petitions and petitions related to ANDA[2], certain NDAs[3], or certain BLAs[4]	220	1	220	24	5,280
10.33; administrative reconsideration of action	6	1	6	10	60
10.35; administrative stay of action	6	1	5	10	50
10.65; meetings and correspondence	750	1	750	5	3,750
10.85; requests for Advisory opinions	4	1	4	16	64
10.115(f)(3); submitting draft guidance proposals	100	1	100	4	400
12.22--Filing objections and requests for a hearing on a regulation or order	5	1	5	20	100
12.45--Notice of participation	5	1	5	3	15
Total			1,096		9,720

[1.] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2.] Abbreviated New Drug Applications
[3.] New Drug Applications
[4.] Biologic License Applications

Unless a waiver, suspension, or modification submitted under § 10.19 (21 CFR 10.19) is granted by the Commissioner of Food and Drugs (the Commissioner), the regulations in 21 CFR part 10 apply to all petitions, hearings, and other administrative proceedings and activities conducted by FDA. Because we have not received requests under § 10.19, we had not included this provision in the information collection. However, to reflect the attendant burden resulting from submitting such a request, we provide an estimate of 1 response and 1 burden hour annually.

Administrative proceedings may be initiated under § 10.25 when a petition is submitted. Section 10.30 sets forth procedures by which an interested person may submit a citizen petition requesting the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. Similarly, section 10.31 governs citizen petitions and petitions for stay of action related to abbreviated new drug applications, certain new drug applications, or certain biologics license applications issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(a)). The regulations provide content, format, and procedural requirements applicable to the submission of these petitions. We characterize the *certification* and *verification* required under sections 10.31(c) and (d), respectively, as both, not a *collection of information* as defined under 5 CFR 1320.3(c)(2) because the prescribed language is a "*public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public . . .*''; and excluded from the definition of *information* consistent with 5 CFR 1320.(h)(1) regarding "*[a]ffidavits, oaths, affirmations, certifications, receipts, changes of address, consents, or acknowledgments*." Based on our review, an average of 220 citizen petitions are received annually under §§ 10.30 and 10.31, and we estimate an average of 24 hours is required to prepare such a petition, for a total of 5,280 hours annually.

The regulations also establish a means by which an interested person may request that part or all of a decision by the Commissioner be reconsidered, or that the effective date of an action be stayed or extended. Sections 10.33 and 10.35 establish the content, format, and procedural requirements applicable to such requests and explain that they must be submitted no later than 30 days after the decision involved. The regulations provide alternatively that, for good cause, the Commissioner may permit a petition to be filed after 30 days. The regulations also explain that an interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. According to our records, we have received a total of 12 such requests and we assume it takes respondents an average of 10 hours to prepare.

Section 10.65 covers FDA meetings and correspondence. Interested persons may hold meetings and exchange correspondence with FDA representatives on matters within its jurisdiction by following the instructions and providing the information described in § 10.65. Because FDA maintains other information collections in its inventory that cover specific types of meeting requests, we did not previously include burden that may result from this section. However, to account for burden associated with meeting requests and correspondence generally, we provide an estimate of 2,000 submissions annually under this information collection; we assume one respondent per submission; and we assume each submission requires respondents anywhere between 1 to 10 hours to prepare, including gathering and reviewing the necessary material. We therefore use an average of 5 hours for this estimate and base this estimate on our experience with similar information collection.

Section 10.85, issued under section 701(a) of the FD&C Act, sets forth content, format, and procedural requirements by which an interested person may request an advisory opinion

from the Commissioner on a matter of general applicability. The regulation explains that, when making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Based on our data, we estimate 4 such requests are received each year and we assume each request requires 16 hours to prepare, for a total of 64 hours annually.

Section 10.115(f)(3) provides for the public submission of draft guidance documents or topics for development to our Dockets Management Staff. To participate in the development and issuance of guidance documents, the public may elect to submit comment through alternative mechanisms as explained in our Good Guidance Practice regulations under § 10.115. Although most submissions and attendant burden associated with recommendations found in FDA guidance documents is accounted for in individual information collections associated with a particular product area or regulatory topic, here we are accounting for burden associated with general public submissions as described in § 10.115(f)(3). Based on our data, we receive an average of 100 such submissions each year; we assume each submission requires an average of 4 hours to prepare; and therefore calculate a total burden of 400 hours annually.

Regulations in 21 CFR 12.20 (§ 12.20) include information collection associated with requesting a formal evidentiary public hearing, and are issued under section 701(e)(2) of the FD&C Act. The regulations provide instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and does not limit the evidence that may be presented if a hearing is granted. We estimate 5 respondents will file a request under the regulation and assume each request requires 20 hours to prepare, for a total of 100 hours annually.

Finally, section 12.45 (21 CFR 12.45), issued under section 701 of the FD&C Act, sets forth content, format, and procedural requirements for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e) the presiding officer may omit a participant's appearance. Based on our records,

we estimate 5 filings under this regulation and assume it requires 3 hours to prepare, for a total of 15 hours annually.

12b. Annualized Hour Cost Estimate

We estimate an average cost of $100,000 annually for the information collection by multiplying the total annual hours (9,720) by a factor of $10/hr in excess of the Federal minimum wage in to include costs of mailing and copying that may be incurred if applicable.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

We estimate the annual cost to the Federal government to be $305,510 annually, by multiplying the number of submissions (1,096) by an hourly wage rate of $55.75 61,102), to reflect the Washington D.C. area salary of a GS-13/5 FTE who would process the submission. We then multiply this figure by a factor of 5 to account for loaded costs.

15. Explanation for Program Changes or Adjustments

The information collection reflects changes and adjustments. We have revised the information collection to account for burden that we attribute to 21 CFR 10.19 regarding waiver requests; 21 CFR 10.65 regarding general meeting requests and correspondence; 21 CFR 10.115 regarding general guidance suggestions for FDA development or withdrawal; and 21 CFR 10.31 and supporting guidance on certain citizen petitions and petitions for stay of agency action association with 505(q) of the FD&C Act. This results in an overall increase to the collection by 4,526 hours and 869 responses annually.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish this collection of information.

17. Reason(s) for Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to the Certification under 5 CFR 1320.9

There are no exceptions to the certification.